R E M A R K S

The Office Action of February 6, 2002, presents the examination of claims 1-10, 16-23, and 28-30. Claims 1-10, 17-18, 23, and 30 are amended. Support for the amendments to claims 1 and 30 is found in the specification, particularly on page 8, lines 7-10, and in Examples 1-7. Support for the amendments to claims 2-10 and 17-18 is found on page 7, lines 20-22 of the specification and in claim 1. Claim 23 is amended to correct a typographical error.

A marked-up version showing changes made to the specification and the claims is attached hereto, as well as a copy of all pending claims as amended. No new matter is inserted into the application.

Office Communication

The Office communication dated August 19, 2002 states that the Reply under 37 C.F.R. § 1.111 filed on June 6, 2002 is non-responsive because the clean copy of claim 30 on pages 6-7 of the Reply does not correspond with the marked-up copy of claim 30 on pages 25-26 of the Reply. In response to the Examiner's remarks, Applicants re-submit the Reply with a corrected version

of claim 30. Entry of the Reply into the record is respectfully requested.

Specification

The Examiner objects to the Coding Table found on page 23 of the specification for allegedly being confusing. In response to the Examiner's remarks, Applicants amend the title of the Coding Table to "Table 1" as suggested by the Examiner. Further, Applicants amend the paragraph on page 23, lines 13-25 into a more clearly structured and labeled table as suggested by the Examiner. Thus, the instant rejection is overcome.

Rejection Under 35 U.S.C. § 101/112, first paragraph

The Examiner rejects claims 1-10, 16-23, and 28-30 under 35 U.S.C. § 101 for an alleged lack of either a specific or substantial asserted utility or a well-established utility. Further, the Examiner rejects the same claims under 35 U.S.C. § 112, first paragraph for allegedly not being enabled by the specification, since the claims allegedly lack utility. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the specification provides no evidence which shows or suggests that the encoded proteins actually function as raffinose synthase enzymes. Applicants respectfully disagree with the Examiner's assertions and submit that the Examiner has made an improper rejection under 35 U.S.C. § 101/112, first paragraph.

First, Applicants point out to the Examiner that he has the burden of providing evidence or reasoning showing or suggesting that the encoded proteins would *not* function as raffinose synthase enzymes. The Examiner cannot simply assert that he believes the utility to be incredible without any evidence or reasoning backing up that assertion. "Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to asserted utility, unless evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement." U.S. Pat. & Trademark Off., *Manual Pat. Examining Proc.* § 2107 (8th ed. 2001). In the instant case, the Examiner has offered no evidence or reasoning suggesting that the nucleotides encoding the proteins of the present invention would not function as raffinose synthase enzymes.

As noted in the "Revised Interim Utility Guidelines Training Materials" issued by the USPTO, if the Examiner doubts that a nucleic acid has the biological function asserted by Applicants, it is incumbent upon the Examiner to find via a search a nucleic acid, which possesses high homology with the nucleotide sequences disclosed in the present application, but encodes an enzyme other than a raffinose synthase. U.S. Pat. & Trademark Off., *Revised Interim Util. Guidelines Training Materials* (2000). Based upon the record and the lack of such a search, the Examiner has provided no reason to doubt Applicants' disclosure that the instant nucleotide sequences encode raffinose synthase proteins. See, Example 10 of *Revised Interim Util. Guidelines Training Materials* (2000).

Second, based upon the record, Applicants have asserted there is a well-established utility for these nucleotides. Specifically, it is known in the art that raffinose synthase enzymes catalyze the synthesis of raffinose, which is responsible for meteorism and absorption disorders in mammals (see pages 1 and 2 of the specification). The present invention is directed to the raffinose synthase enzyme, and nucleic acids encoding the raffinose synthase enzyme, and a method for controlling the expression level of raffinose synthase in plants

using, for example, an antisense construct of the raffinose synthase nucleic acid. Therefore, absent evidence to the contrary, it would be expected that the nucleic acids disclosed in the specification would be useful for controlling the expression level of raffinose synthase in plants, with the further expectation that the modified plants would be used to feed animals without producing meteorism or absorption disorders.

For these reasons, the Examiner has failed to establish a *prima facie* case of lack of utility/enablement. Thus, the rejection under 35 U.S.C. § 101/112, first paragraph for lack of utility/enablement is improper and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1, 16-23, and 28-30 under 35 U.S.C. § 112, first paragraph for an alleged lack of written description in the specification. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Basically, the Examiner appears to assert that the claims are too broad for the amount of disclosure found in the specification. In making the instant rejection, the Examiner

relies upon the holding of University of California v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed. Cir. 1997). However, Applicants wish to point out at the very beginning that the facts of the present application are very different from the facts in Lilly.

First, the claim in Lilly encompassed all "mammalian" insulin genes, even though the specification only completely described a single gene (encoding rat insulin) and **poorly** described a process for obtaining additional insulin genes (plating clones, picking them and sequencing them to determine if the cDNA encoded an insulin gene).

In contrast, the present application describes **a plurality** of isolated nucleic acids which encode raffinose synthase (SEQ ID NOS:2, 4, 6, and 8) and furthermore provides a description of a method for obtaining an isolated nucleic acid encoding raffinose synthase derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants by performing a PCR reaction with one or more of a number of upstream and downstream primers.

Thus, the claimed nucleic acids of the present invention are those derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants, whereas the nucleic acids claimed in Lilly comprised

gene from all vertebrates. As such, the facts of the present application are very different from the facts in Lilly, and application of said case to the present application is unmerited.

The function of the written description requirement is to assure that the inventor in fact had the claimed invention in his possession at that time the application was filed. U.S. Pat. & Trademark Off., *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement* (2001). In the instance of the Lilly case, it was clear that at the time the application was filed, the inventors did not possess the invention broadly. They had isolated but a single insulin gene, and that from a rat, an organism that was not really of interest to the pharmaceutical industry, with the future desire to use human genes and gene products. The broad claim to genes encoding "mammalian" insulin was a bald attempt to extend the limited attainments of the inventors to cover the invention that was of real value.

On the other hand, in the present application the inventors have described four variant cDNAs, obtained from four different plant species that encode proteins having the desired activity. The inventors have further provided examples of PCR primers and detailed description of how to use them to isolate additional

examples of isolated DNA encoding raffinose synthase from other species. Working examples (1-7) of use of the PCR primers to perform such isolations are provided. This disclosure is much more than a "mere statement that [broadly claimed DNA] is part of the invention and reference to a potential method of isolating it." Fiers v. Sugano, 25 USPQ2d 1601 (Fed. Cir. 1993). This disclosure constitutes actual variants within the claimed genus and actual methods that can be used to find the next species within the genus. Furthermore, the demonstration of isolation of three additional species of cDNA within the scope of the claims, starting from a first one obtained by the inventors, establishes predictability of obtaining additional species.

The inventors have further provided description of an assay that can be used to determine if the protein encoded by any gene isolated by the method of the Example in fact is a functional raffinose synthase. See, page 31, line 22 to page 33, line 9 of the specification wherein detailed instructions for measuring raffinose synthase activity are disclosed.

Clearly the present application "convey[s] the information that an application has invented the subject matter which is claimed." Thus, the rejection of claims 1, 16-23, and 28-30 under

35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description of the claimed invention, should be withdrawn.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 1, 16-22, and 28-30 under 35 U.S.C. § 102(e) for allegedly being anticipated by Osumi '292 (U.S. Patent 6,166,292). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Osumi '292 discloses isolated DNAs which originate from an organism having an ability to produce raffinose from sucrose and galactinol. One such DNA (SEQ ID NO:4) codes for a protein which has the amino acid sequence of SEQ ID NO:5. The Examiner argues that the isolated nucleic aids of the instant claim 1 would inherently be hybridizable under a "low or moderately" stringent condition to the coding region of SEQ ID NO:4, as disclosed by Osumi '292. Applicants respectfully disagree.

Claim 1, as amended, recites an isolated nucleic acid which comprises a polynucleotide derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants. As acknowledged by the Examiner, the DNAs disclosed by Osumi '292 originate from cucumber. However, the

isolated nucleic acids recited in claim 1 originate from soybean, *Chenopdiaceae* plants or *Cruciferea* plants. As such, the subject matter disclosed by Osumi '292 falls outside of the instant claim scope. Withdrawal of the instant rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejects claim 23 under 35 U.S.C. § 103(a) for allegedly being obvious over Osumi '292. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

As described in Example 4 of Osumi '292, the raffinose synthase expressed therein is a protein encoding the amino acid sequence of SEQ ID NO:5 in Osumi '292. Since the protein of Osumi '292 is distinct from the protein expressed from the genes of claims 1 and 30 as amended, the transformant expressing the protein of Osumi '292 is also distinct from the transformant of claim 23 in the present application.

Further, Osumi '292 provides no suggestion to modify the transformant expressing the protein of Osumi '292 into the transformant of claim 23 in the present application. The protein of Osumi '292 originates from cucumber, and the term

"cucumber" would not suggest soybean, Chenopdiaceae plants or Cruciferea plants. The transformant expressing the protein of Osumi '292 would not suggest the transformant of claim 23 in the present application. Therefore, the method of claim 23 would not be obvious over Osumi '292. Withdrawal of the instant rejection is respectfully requested.

Obviousness-Type Double Patenting

The Examiner provisionally rejects claims 1, 16-23, and 28-30 under the doctrine of double patenting for allegedly being unpatentable over claims 5-7 and 21 of copending U.S. Application No.: 09/612,095. Claims 1, 16-22, and 28-30 are provisionally rejected under the doctrine of double patenting for allegedly being unpatentable over claims 40-49, 54-55, and 58 of copending U.S. Application No.: 09/415,918. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

First, Applicants point out that U.S. Application No.: 09/415,918 has been abandoned, thus rendering a rejection over this reference moot.

Second, copending U.S. Application No.: 09/612,095 has not issued. Thus, Applicants reserve the right to answer this

rejection once either the present application or copending U.S. Application No.: 09/612,095 is issued by the United States Patent and Trademark Office.

Conclusion

Applicants respectfully submit that all of the pending rejections have been addressed and overcome by the above remarks and/or amendments. All of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of one (1) month to June 6, 2002, in which to file a reply to the Office Action. The required fee of $110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any

additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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ATTACHMENT: VERSION WITH MARKINGS TO SHOW CHANGES MADE
PENDING CLAIMS (AS AMENDED)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph on page 23, lines 13-25, of the specification is amended as follows:

Table 1: Coding Table

[Phe: UUU, UUC Ser: UCU, UCC, UCA, UCG, AGU, AGC

Tyr: UAU, UAC Cys: UGU, UGC

Stop: UAA, UAG, UGA Trp: UGG

Leu: UUA, UUG, CUU, CUC, CUA, CUG Pro: CCU, CCC, CCA, CCG

His: CAU, CAC Gln: CAA, CAG Arg: CGU, CGC, CGA, CGG, AGA, AGG

Ile: AUU, AUC, AUA Thr: ACU, ACC, ACA, ACG

Asn: AAU, AAC Lys: AAA, AAG

Met: AUG

Val: GUU, GUC, GUA, GUG Ala: GCU, GCC, GCA, GCG

Asp: GAU, GAC Gly: GGU, GGC, GGA, GGG

Glu: GAA, GAG]

AMINO ACID	CODON 1	CODON 2	CODON 3	CODON 4	CODON 5	CODON 6
Phe	UUU	UUC				
Ser	UCU	UCC	UCA	UCG	AGU	AGC
Tyr	UAU	UAC				
Cys	UGU	UGC				
Stop	UAA	UAG	UGA			
Trp	UGG					
Leu	UUA	UUG	CUU	CUC	CUA	CUG

Pro	CCU	CCC	CCA	CCG		
His	CAU	CAC				
Gln	CAA	CAG				
Arg	CGU	CGC	CGA	CGG	AGA	AGG
Ile	AUU	AUC	AUA			
Thr	ACU	ACC	ACA	ACG		
Asn	AAU	AAC				
Lys	AAA	AAG				
Met	AUG					
Val	GUU	GUC	GUA	GUG		
Ala	GCU	GCC	GCA	GCG		
Asp	GAU	GAC				
Gly	GGU	GGC	GGA	GGG		
Glu	GAA	GAG				

IN THE CLAIMS:

The following claims are amended:

1. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] which comprises a polynucleotide derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants, said polynucleotide having a nucleotide sequence hybridizable with a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1,

(b) a [the] nucleotide sequence as depicted in SEQ ID NO: 2,

(c) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3,

(d) a [the] nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4,

(e) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5,

(f) the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6,

(g) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7, [and

(h) the nucleotide sequence depicted by the 1st to the 1719th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 8,]

under conditions equivalent to 42°C to 68°C in a buffer comprising 0.9M NaCl 0.09M citric acid, and encoding a protein that binds a [being capable of binding] D-galactosyl group through the α (1→6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose.

2. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1.

3. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising the nucleotide sequence as depicted in SEQ ID NO: 2.

4. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3.

5. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising the nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4.

6. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5.

7. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6.

8. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7.

9. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising the nucleotide sequence depicted by the 1st to 1719th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 8.

10. (Twice Amended) An isolated nucleic acid [raffinose synthase gene] comprising the nucleotide sequence as depicted in SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8.

17. (Twice Amended) A vector comprising the nucleic acid [raffinose synthase gene] of claim 1.

18. (Twice Amended) A transformant, wherein the nucleic acid [raffinose synthase gene] of claim 1 is introduced into a host cell.

23. (Twice Amended) A method for producing a raffinose synthase which comprises the steps of:

culturing or growing the transformant of claim 18 to produce the raffinose synthase, and

collecting the raffinose synthase.

30. (Amended) The isolated nucleic acid [raffinose synthase gene of claim 1, wherein the hybridization temperature is] which comprises a polynucleotide derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants, said polynucleotide having a nucleotide sequence hybridizable with a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1,

(b) a nucleotide sequence as depicted in SEQ ID NO: 2,

(c) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3,

(d) a nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4,

(e) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5,

(f) the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6, and

(g) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7,

under conditions equivalent to 65°C to 68°C in a buffer comprising 0.9M NaCl 0.09M citric acid, and encoding a protein that binds a D-galactosyl group through the α (1→6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose.

PENDING CLAIMS (AS AMENDED)

1. (Twice Amended) An isolated nucleic acid which comprises a polynucleotide derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants, said polynucleotide having a nucleotide sequence hybridizable with a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1,

(b) a nucleotide sequence as depicted in SEQ ID NO: 2,

(c) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3,

(d) a nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4,

(e) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5,

(f) the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6,

(g) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7,

under conditions equivalent to 42°C to 68°C in a buffer comprising 0.9M NaCl 0.09M citric acid, and encoding a protein that binds a D-galactosyl group through the α (1→6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose.

2. (Twice Amended) An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1.

3. (Twice Amended) An isolated nucleic acid comprising the nucleotide sequence as depicted in SEQ ID NO: 2.

4. (Twice Amended) An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3.

5. (Twice Amended) An isolated nucleic acid comprising the nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4.

6. (Twice Amended) An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5.

7. (Twice Amended) An isolated nucleic acid comprising the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6.

8. (Twice Amended) An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7.

9. (Twice Amended) An isolated nucleic acid comprising the nucleotide sequence depicted by the 1st to 1719th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 8.

10. (Twice Amended) An isolated nucleic acid comprising the nucleotide sequence as depicted in SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8.

16. (Twice Amended) An isolated nucleic acid comprising a nucleic acid of claim 1, which is joined to a promoter.

17. (Twice Amended) A vector comprising the nucleic acid of claim 1.

18. (Twice Amended) A transformant, wherein the nucleic acid of claim 1 is introduced into a host cell.

19. A transformant, wherein the nucleic acid of claim 16 is introduced into a host cell.

20. A transformant, wherein the vector of claim 17 is introduced into a host cell.

21. (Twice Amended) The transformant of claim 18, wherein the host cell is a microorganism.

22. (Twice Amended) The transformant of claim 18, wherein the host cell is a plant cell.

23. (Twice Amended) A method for producing a raffinose synthase which comprises the steps of:

culturing or growing the transformant of claim 18 to produce the raffinose synthase, and

collecting the raffinose synthase.

28. The nucleic acid of claim 16, wherein said promoter is effective in a plant cell.

29. The nucleic acid of claim 16, wherein said promoter is effective in a yeast cell.

30. (Amended) The isolated nucleic acid which comprises a polynucleotide derived from a plant selected from the group consisting of soybean, *Chenopdiaceae* plants and *Cruciferea* plants, said polynucleotide having a nucleotide sequence hybridizable with a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 1,

(b) a nucleotide sequence as depicted in SEQ ID NO: 2,

(c) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3,

(d) a nucleotide sequence depicted by the 236th to 2584th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4,

(e) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5,

(f) the nucleotide sequence depicted by the 134th to 2467th nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6, and

(g) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7,

under conditions equivalent to 65°C to 68°C in a buffer comprising 0.9M NaCl 0.09M citric acid, and encoding a protein that binds a D-galactosyl group through the α (1→6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose.